JUN 1 6 2010

Blue Egg Co.

510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

Submission Information

US Agent:

Official Correspondent:	Hong Jung Hyun (Mr.)
	216-5 Yongmoon-Dong, Seo-Ku, Daejon, Korea
Sponsor:	Blue Egg Co.
	216-5 Yongmoon-Dong, Seo-Ku, Daejon, Korea
Manufacturing Site	Blue Egg Co.
	216-5 Yongmoon-Dong, Seo-Ku, Daejon, Korea

Device Identification

Proprietary Name:	Unimom Allegro
Common/Usual Name:	Powered Breast Pump
Classification Name:	Powered Breast Pump per 21 CFR § 884.5160
Product Code:	HGX

Substantially Equivalent Predicate Legally Marketed Device

The subject device, Unimom Allegro, is substantially equivalent in technical characteristics and intended used to:

Device Name	Medela Swing ™ Breastpump	Medela Mini Electric
510(k) Number	K053052	K901344

Device Description

The Unimom Allegro electric breast pump is intended to express the mother's milk of a lactating woman. The pumping can be only on one breast at the time. The Unimom Allegro electric breast pump can operate off common batteries or off a DC POWER supply. The Unimom Allegro electric breast pump's drive unit employs a diaphragm-type vacuum pump, powered by a DC-motor, supervised by a microcontroller. Passing

through an air tubing to breastshield, the vacuum is used to comfortably draw out the breast milk. This device is designed with 7 vacuum levels by pressing button.

Indications for Use

The Unimom Allegro is intended to express breast milk from the breast of lactating woman.

Comparison to leally marketed predicate device

The Unimom Allegro has the same intended use and similar technological characteristics as the predicate device. Thus, we are claiming that the Unimom Allegro is substantially equivalent to the predicate device.

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Blue Egg Co. concludes that the Unimom Allegro are safe and effective and substantially equivalent to predicate devices as described herein.

Blue Egg Co. will update and include in this summary any other information deemed reasonably necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Blue Egg Co.
c/o Marc M. Mouser
Office Coordinator
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607

JUN 16 2010

Re: K100929
Trade Name: Unimom Allegro
Regulation Number: 21 CFR § 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: May 25, 2010
Received: June 3, 2010

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

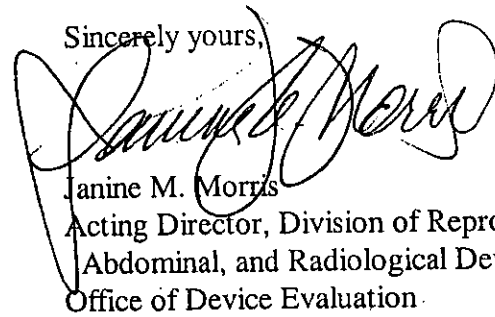
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100929

Device Name: Unimom Allegro

Indications for Use:

The Unimom Allegro is intended to express breast milk from the breast of a lactating woman.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _√_ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 3-1
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K100929